



700003741 | NF-105

Product Instructions

Neogen® Soleris® Total Viable Count, UHT

Product Instructions

Total Viable Count, UHT

Product Description and Intended Use

The Neogen® Soleris® Total Viable Count, UHT vial (NF-105) is used with the Neogen® Soleris® Next Generation instrument (SNG-INS32, SNG-INS32CS or SNG-INS64CS). The Total Viable Count, UHT is a 5 mL filled vial. As organisms grow in the broth medium, the carbon dioxide (CO₂) produced diffuses through a membrane layer into a soft agar plug containing a dye indicator. The Soleris instrument reads the color change in the dye. The membrane layer also serves as a barrier, eliminating product interference with the reading frame.

The Total Viable Count, UHT vial is intended to provide rapid detection of microbial contaminants in Ultra High Temperature (UHT) processed and aseptically filled products for the purposes of commercial sterility testing. These include products such as UHT treated milk and dairy alternative drinks. NF-105 vials permit the growth and detection of aerobic, mesophilic microorganisms in UHT liquid products. This includes bacteria, yeast, and molds, and especially spore-forming bacteria, which could survive the UHT heat process.

Safety

The user should read, understand, and follow all safety information in the instructions for the Neogen Soleris NF-105 vial. Retain the safety instructions for future reference.

⚠ WARNING: Indicates a hazardous situation, which, if not avoided, could result in death or serious injury with or without the potential for property damage.

NOTICE: Indicates a potentially hazardous situation which, if not avoided, could result in property damage.

⚠ WARNING

To reduce the risks associated with exposure to biohazards and environmental contamination:

- Follow current industry standards and local regulations for disposal of biohazardous waste.

To reduce the risks associated with release of contaminated product:

- Follow all product storage instructions contained in the instructions for use.
- Do not use beyond the expiration date.

To reduce the risks associated with bacterial infection and workplace contamination:

- Perform Neogen Soleris NF-105 testing in a properly equipped laboratory under the control of a skilled microbiologist.
- The user must train its personnel in current proper testing techniques: for example, Good Laboratory Practices¹, ISO 7218², or CDC Biosafety in Microbiology and Biomedical Laboratories (BMBL)³, and/or applicable regional biosafety directives or guidelines.

To reduce the risks associated with misinterpretation of results:

- Do not use Neogen Soleris in the diagnosis of conditions in humans or animals.
- Specific product matrices may require new test parameters. For all cases below, an adjustment of the test procedure and/or the parameters would be required. Contact Neogen Technical Services for additional information.

- Matrices with a negative impact on microbial growth, such as food containing preservatives, may require an extension to the preincubation time and/or test duration. Consult Neogen Technical Services for guidance.
- Certain matrices could have an impact on the vial plug, this may result in an early detection closely following the shuteye period even if the food sample is negative e.g., acidic food samples without pH adjustment could present a matrix impact.
- Products containing CO₂ releasing compounds (e.g., ascorbic acid, calcium carbonate, or calcium ascorbate) need to be carefully validated as reactions with the vial chemistry may occur, causing false-positive results.
- Information provided is based on validation procedures that Neogen performed in Neogen laboratories. Deviation from procedures is possible, but should be discussed with Neogen technical services.
- Some samples may need to be pH-adjusted. Refer to the pH adjustment procedure below to determine if the matrix has an impact on the pH of the vial. In most cases, pH adjustment is not necessary but should be assessed during verification.
- Some strains do not detect within the recommended test duration and will need an extended test duration. These organisms may have been strain-specific or described as being temperature sensitive.

User Responsibility

Users are responsible for familiarizing themselves with product instructions and information. Visit our website at www.neogen.com, or contact your Neogen representative or authorized distributor for more information.

When selecting a test method, it is important to recognize that external factors such as sampling methods, testing protocols, sample preparation, handling, and laboratory technique may influence results.

It is the user's responsibility in selecting any test method or product to evaluate a sufficient number of samples with the appropriate matrices and microbial challenges to satisfy the user that the chosen test method meets the user's criteria.

It is also the user's responsibility to determine that any test methods and results meet its customers' and suppliers' requirements.

As with any test method, results obtained from use of any Neogen Food Safety product do not constitute a guarantee of the quality of the matrices or processes tested.

Limitation of Warranties / Limited Remedy

EXCEPT AS EXPRESSLY STATED IN A LIMITED WARRANTY SECTION OF INDIVIDUAL PRODUCT PACKAGING, NEOGEN DISCLAIMS ALL EXPRESS AND IMPLIED WARRANTIES, INCLUDING BUT NOT LIMITED TO, ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE. If any Neogen Food Safety Product is defective, Neogen or its authorized distributor will, at its option, replace or refund the purchase price of the product. These are your exclusive remedies. Please contact your Neogen representative or authorized Neogen distributor for any further questions.

Limitation of Neogen Liability

NEOGEN WILL NOT BE LIABLE FOR ANY LOSS OR DAMAGES, WHETHER DIRECT, INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING BUT NOT LIMITED TO LOST PROFITS. In no event shall Neogen's liability under any legal theory exceed the purchase price of the product alleged to be defective.

Storage

Store the Neogen Soleris NF-105 vials at temperatures between 2-8°C. Allow the vials to reach room temperature before adding the sample. Return unused vials to the box and place them back into 2-8°C storage. Vials are usable up to their expiration date.

Do not use Neogen Soleris NF-105 vials that have yellow plugs or turbidity in the broth media. Expiration date and lot number can be located on the Neogen Soleris NF-105 box label and on the individual vial label..

△ Disposal

After use, the Neogen Soleris NF-105 vials may contain microorganisms that may be a potential biohazard. Follow industry standards and applicable regulations for disposal.

Instructions for Use

Follow all instructions carefully. Failure to do so may lead to inaccurate results.

For validated methods, see **Specific Instructions for Validated Methods**.

Sample Preparation

1. Prepare the sample according to one of the following
 - a. For commercial sterility testing, incubate the sample (whole product up to 1 L carton) for 48-72 hr at 30°C (MicroVal certified method) or 32-37°C.
 - b. For direct inoculation, the sample can be directly added into the vial.
 - c. For dilute to specification, create a 1:10 dilution by adding 10 g of the sample to 90 mL of Butterfield's Phosphate Buffer (BPB) or 11 g of the sample to 99 mL of BPB. Complete further dilution as necessary in Butterfield's Phosphate Buffer.
2. Mix thoroughly by shaking the sample.
3. Check pH and adjust if necessary by following one of the procedures listed below.

Inoculation of Vial

1. Add sample volume for the following
 - a. For commercial sterility testing, transfer 5 mL of the incubated sample into the vial
 - b. Direct inoculation, add up to 5 mL of the matrix directly
 - c. For dilute to specification, add 1 mL into the vial or the volume of the appropriate dilution required.
2. Add 0–5 mL of BPB or sterile deionized water to the vial to bring the total added volume up to 5 mL, based on the amount of sample added to the vial.
3. Cap the vial and gently invert three times to mix the sample. Keep the cap tight.
4. Insert the vial into the Soleris instrument utilizing the applicable algorithm below. Adjusting parameters without consulting Neogen Technical Services is not recommended

pH Adjustment Procedure

1. In Soleris Vial

This procedure should be performed on a sample in the vial that will not go through the full testing procedure to determine if a pH adjustment is required.

- a. Add up to 5 mL of the sample directly into the vial.
- b. Cap the vial and gently invert 3 times to mix the sample.
- c. Insert the pH probe into the vial and record the pH once it has stabilized. If out of specification, add acid or base until the pH is within 7.3 ± 0.2 .
- d. The same amount of acid or base used can then be used for the same sample type going forward.

2. In Sample Dilution

- a. Remove a small aliquot from the diluted sample. Once removed, the portion being used for pH testing should not be added back to the sample.
- b. Check the starting pH with either pH test strips or a pH meter. If using a pH meter, allow the reading to stabilize before recording.
- c. If out of specification, add acid or base to the sample until the pH is within 7.0 ± 1.0 .
- d. The same amount of acid or base used can then be used to adjust the same volume of that sample type going forward.

Different testing procedures can be used depending on current local reference methods, some of which are listed in the section below titled **Specific Instructions for Validated Methods**.

Preparation of the Neogen Soleris Next Generation Instrument

1. Launch the Neogen Fusion software and log in. Contact your Neogen Food Safety representative to ensure you have the most updated version of the software.
2. Verify the appropriate test parameters are set per the table below. Refer to the Neogen Soleris Software User Guide for details.

Test Parameters

	Test	Threshold	Skip	Shuteye	Test Duration	Temperature
Commercial Sterility	NF-105	10	1	70	24 hours	30°C
Direct inoculation/ dilute to specification	NF-105	10	2	30	24 hours	32-35°C

Note: it is possible to incubate the vial in a traditional static incubator at $30 \pm 1^\circ\text{C}$ for a minimum of 24 hours and then utilize the EndPoint reading functionality. Contact Neogen technical services for further guidance and support.

Interpretation

The Fusion Software will signal a positive result if the optical signal meets the algorithm criteria. Positive results will generally be detected in less than 24 hours. If the Fusion software does not signal a detection during the test duration, the sample is considered negative.

Confirmation (Optional)

1. Remove the positive (detecting) Soleris NF-105 vial from the instrument.
2. Transfer 0.1 mL to Plate Count Agar (PCA) (Neogen Item NCM0010 or equivalent) plate and streak for isolation
3. Incubate the PCA plate at 30-35°C for up to 72 hours

Specific Instructions for Validated Methods

MicroVal Certification



Microval certificate number 2021LR100 in compliance with ISO 16140-24 in comparison to European Regulation (EC) 853/2004 (Section IX) or Codex Alimentarius Code of Hygiene Practice for Milk and Milk Products (CAC/RCP 57-2004)5, using ISO 4833-1:2013 for the plate count at 30°C

Use the following details when implementing the above Instructions for Use:

Scope of the validation:

UHT treated milk and dairy alternative drinks

Sample Preparation:

1. Incubate the sample (up to 1 L carton) at 30 °C for 48-72 h.
2. Mix thoroughly by shaking the sample.

Inoculation of Vial

1. Add 5 mL of the sample directly to the vial.
2. Cap the vial and gently invert three times to mix the sample. Keep the cap tight.
3. Insert the vial into the Soleris instrument utilizing the applicable algorithm below.

Test	Threshold	Skip	Shuteye	Test Duration	Temperature
NF-105	10	1	70	24 hours	30°C

Interpretation

The Fusion Software (version 1.6 or above) will signal a positive result if the optical signal meets the algorithm criteria. Positive results will generally be detected in less than 24 hours. If the Fusion software does not signal a detection during the test duration, the sample is considered negative.

References

1. U.S. Food and Drug Administration. Code of Federal Regulations, Title 21, Part 58. Good Laboratory Practice for Nonclinical Laboratory Studies.
2. ISO 7218:2024. Microbiology of food and animal feeding stuffs – General requirements and guidance for microbiological examinations.
3. CDC Biosafety in Microbiological and Biomedical Laboratories (BMLB) 6th Edition. Effective Date: 29 August 2025
4. ISO 161402:2016. Microbiology of the food chain – Method Validation – Protocol for the validation of alternative (proprietary) methods against a reference method.
5. Codex Code of Hygienic practice for milk and milk products (CAC/ RCP 57-2004). Annex B Microbiocidal control measures Section 2.2 process management for UHT treatment using ISO 4833-1:2013 for the plate count at 30 °C
6. ISO 4833-2:2013. Microbiology of the food chain — Horizontal method for the enumeration of microorganisms — Part 2: Colony count at 30°C by the surface plating technique
7. Diep, Benjamin, et al. “Validation protocol for commercial sterility testing methods.” Food control 103 (2019): 1-8
8. Mozola, Mark, et al. “Validation of the Soleris® NF-TVC method for determination of total viable count in a variety of foods.” Journal of AOAC International 96.2 (2013): 399-403

Refer to the current versions of the standard methods listed above.

Explanation of Symbols

info.neogen.com/symbols

Neogen Food Safety

EN (English)

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